Introduction

The risk of patient self-dose administration was studied in multiple sclerosis (MS) by dose response experiments. These experiments showed that higher doses of fingolimod resulted in a higher rate of side effects. The authors of this study aimed to determine if fingolimod 0.5 mg in the extension phase could provide a safe and effective treatment option for patients with relapsing-remitting multiple sclerosis (RRMS).

Methods

The study included 1072 patients with RRMS who were randomized to fingolimod 0.5 mg or 1.25 mg or placebo once daily for 1 year. The primary endpoints were confirmed relapses (M0-12), number of new T2 lesions, and MRI lesion activity (M0-12). All patients then received fingolimod 0.5 mg in an ongoing open-label extension study.

Results

The results showed that fingolimod 0.5 mg was non-inferior to placebo in terms of confirmed relapses and number of new T2 lesions. There was a non-significant trend towards a reduction in MRI lesion activity with fingolimod 0.5 mg compared to placebo.

Conclusions

Fingolimod 0.5 mg in the extension phase was well tolerated and demonstrated a similar safety profile to that observed in the core study. The results support the use of fingolimod 0.5 mg as a treatment option for patients with RRMS.

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Disclosures

The authors have no relevant conflicts of interest to disclose.